

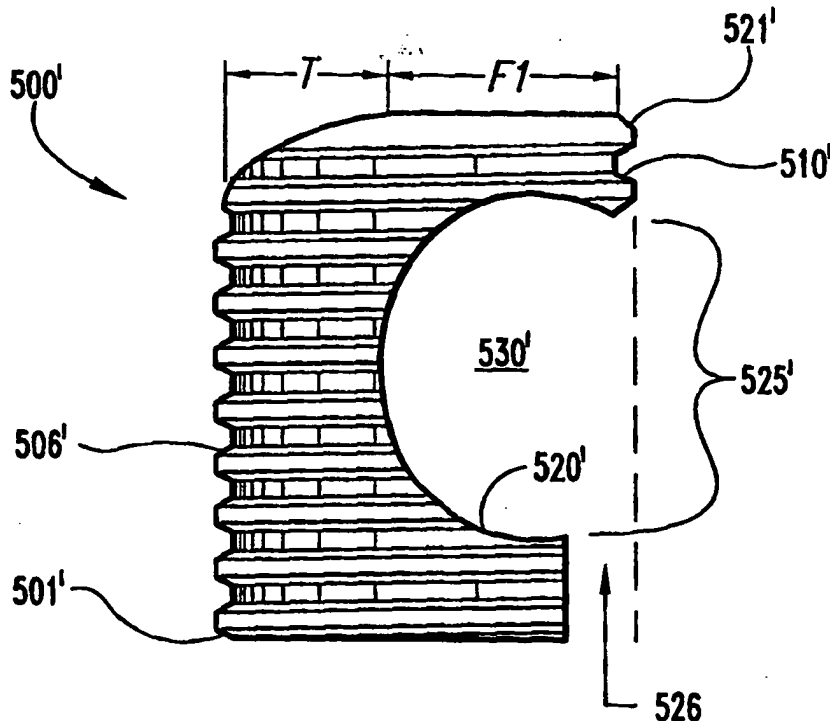
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: OPEN INTERVERTEBRAL SPACER

## (57) Abstract

Open chambered spacers, implanting tools and methods are provided. The spacers (500') include a body (505') having a wall (506') which defines a chamber (530') and an opening (531') in communication with the chamber (530'). In one embodiment the wall (506') includes a pair of arms (520', 521') facing one another and forming a mouth (525') to the chamber (530'). Preferably, one of the arms (520') is truncated relative to the other, forming a channel (526). In one aspect the body (505') is a bone dowel comprising an off-center plug from the diaphysis of a long bone. The tools (800) include spacer engaging means for engaging a spacer and occlusion means for blocking an opening defined in the spacer. In some embodiments, the occlusion means (820) includes a plate (821) extendable from the housing (805). In one specific embodiment the plate (821) defines a groove (822) which is disposed around a fastener (830) attached to the housing (805) so that the plate (821) is slideable relative to the housing (805).



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What is claimed is:

1. A hollow intervertebral spacer, comprising:  
an elongated body having an outer surface and a  
longitudinal axis along a length of said body and defining a  
5 chamber therethrough along a second axis substantially  
perpendicular to said longitudinal axis;  
a first arm connected to said body;  
an opposite second arm connected to said body and facing  
said first arm; and  
10 said first arm and said second arm forming a mouth to  
said chamber.
2. The spacer of claim 1 wherein said body further  
comprises:  
a tool engaging end defining a tool engaging hole for  
15 receiving a driving tool for implanting the spacer.
3. The spacer of claim 2 wherein said anterior surface  
further defines a slot surrounding said tool engaging hole.
4. The spacer of claim 1 wherein said outer surface  
defines threaded bone engaging portions.
- 20 5. The spacer of claim 1 wherein said wall is curved  
and said chamber is substantially C-shaped.
6. The spacer of claim 1 wherein said body is composed  
of a porous material.
7. The spacer of claim 1 wherein said body is composed  
25 substantially of cortical bone.
8. The spacer of claim 1 wherein said first arm is  
truncated relative to said second arm.

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9. The spacer of claim 3 wherein said outer surface defines threaded bone engaging portions and said body is composed of cortical bone.

5 10. The spacer of claim 4 wherein said spacer is a bone dowel obtained from the diaphysis of a long bone having a medullary canal, said chamber including a portion of the canal.

11. The spacer of claim 1, further comprising an osteogenic material packed within said chamber.

10 12. The spacer of claim 11 wherein said osteogenic material comprises autograft, allograft, xenograft, demineralized bone, a calcium phosphate material, a bioceramic, bioglass, an osteoinductive factor or mixtures of thereof.

15 13. An interbody fusion spacer, comprising:  
a body having a wall defining a chamber, the body defining an opening in communication with said chamber, said wall having a first arm and an opposite second arm facing said first arm, said first arm and said second arm forming a  
20 mouth to said chamber, wherein said first arm is truncated relative to said second arm.

14. The spacer of claim 13 wherein said body further comprises:

25 a tool engaging end defining a tool engaging hole for receiving a driving tool for implanting the spacer.

15. The spacer of claim 14 wherein said anterior surface further defines a slot surrounding said tool engaging hole.

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16. The spacer of claim 13 wherein said body further comprises:

an outer surface defining threaded bone engaging surfaces.

5 17. The spacer of claim 13 wherein said wall is curved and said chamber is C-shaped.

18. The spacer of claim 13 wherein said spacer comprises cortical bone.

10 19. The spacer of claim 13 further comprising an osteogenic material packed within said chamber.

20. A graft comprising an elongated body consisting essentially of cortical bone, said body having an outer surface and a longitudinal axis along a length of said body and defining a chamber therethrough along a second axis  
15 substantially perpendicular to said longitudinal axis, said body further defining a channel defined along said longitudinal axis and in communication with said chamber and said outer surface.

20 21. The graft of claim 20 wherein said outer surface defines threaded bone engaging surfaces.

22. The graft of claim 20 further comprising an osteogenic material packed within said chamber.

23. A hollow intervertebral spacer, comprising:  
25 a cylindrical body having a wall, said wall having an outer surface and defining a chamber and an opening in communication with said chamber; and a channel defined in said wall in communication with said chamber and said outer surface.

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24. The spacer of claim 23 wherein said outer surface defines threaded bone engaging portions.

25. A bone graft having a C-shaped wall defining a chamber.

5        26. The spacer of claim 25 wherein said graft is a bone dowel obtained from the diaphysis of a long bone having a medullary canal, said chamber including a portion of the canal.

10       27. A "C"-shaped dowel substantially composed of cortical bone.

28. The "C"-shaped dowel of claim 27 comprising a bone plug obtained from the diaphysis of a long bone, said dowel having a substantially "C"-shaped chamber.

15       29. The "C"-shaped dowel of claim 28 having a chamfered insertion end.

30. The "C"-shaped dowel of claim 28 further comprising a tool engaging end defining an instrument attachment hole.

20       31. The "C"-shaped dowel of claim 30 wherein the tool engaging end also defines a driver slot surrounding said hole.

32. The "C"-shaped dowel of claim 28 further comprising an external feature machined into an outer surface of the dowel.

25       33. The "C"-shaped dowel of claim 32 wherein said feature includes a groove.

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34. The "C"-shaped dowel of claim 32 wherein said feature includes threads formed along a portion of the length of the dowel.

35. The "C"-shaped dowel of claim 27 having a length of  
5 between about 8mm to about 36mm.

36. The "C"-shaped dowel of claim 35 having a diameter of between about 10mm and about 24mm.

37. The "C"-shaped dowel of claim 28 further comprising an osteogenic composition packed within said chamber.

10 38. The "C"-shaped dowel of claim 37 wherein said osteogenic composition comprises autogenous bone, bone morphogenetic protein, a calcium phosphate composition or a mixture of these.

15 39. The "C"-shaped dowel of claim 27 obtained as an off-center transverse plug from the shaft of a donor's fibula, radius, ulna, humerus, femur or tibia.

20 40. A method of making a dowel which comprises machining an off-center transverse plug from the diaphysis of a donor's fibula, radius, ulna, humerus, femur or tibia, said plug having a diameter of between about 10mm and about 24mm and a depth (length) of between about 8mm and about 30mm such that the resulting dowel has, running through it, perpendicular to the long axis of the dowel, a substantially "C"-shaped chamber.

25 41. The method of claim 40 further comprising chamfering one end of said plug to form a generally curved surface for ease of insertion of the dowel into an intervertebral cavity.

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42. The method of claim 40 further comprising machining an instrument attachment hole into one end of the dowel.

43. The "C"-shaped dowel of claim 27 prepared by a process comprising machining an off-center transverse plug from the diaphysis of a donor's fibula, radius, ulna, humerus, femur or tibia, said plug having a diameter of between about 10mm and about 24mm and a length of between 8mm and about 36mm such that the resulting dowel has, running through it, perpendicular to the long axis of the dowel, a substantially "C"-shaped chamber.

44. The "C"-shaped dowel of claim 27 having an outer surface defining a surface feature .

45. The "C"-shaped dowel of claim 44 wherein said feature includes a groove.

46. The "C"-shaped dowel of claim 44 wherein said feature includes threads formed along a portion of the length of the dowel.

47. The "C"-shaped dowel of claim 46 wherein said thread has a pitch of about 0.1".

48. A spacer insertion tool, comprising:  
a housing having a proximal end and an opposite distal end and defining a passageway between said proximal end and said distal end;  
a shaft having a first end and an opposite second end, said shaft disposed within said passageway with said first end adjacent said distal end, said first end defining a spacer engager; and  
an occlusion member extendable from said distal end of

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said housing for blocking an opening defined in the spacer when said spacer engager is engaged to the spacer.

49. The tool of claim 48, further comprising a fastener attached to said shaft and wherein said occlusion member  
5 includes a plate defining a groove, said groove disposed around said fastener so that said plate is slidable relative to said housing.

50. The tool of claim 49 wherein said plate has a curved superior surface which approximates the outer surface  
10 of the spacer when said spacer engaging means is engaged to the spacer and said occlusion means is blocking the opening of the spacer.

51. The tool of claim 48 wherein said shaft is slidably disposed within said passageway.

52. The tool of claim 48 wherein said spacer engager is threaded for mating engagement with a threaded hole in a  
15 spacer.

53. The tool of claim 48 wherein said spacer engager is a hex for mating engagement with an internal hex in a spacer.

54. An insertion tool for inserting a spacer into an intervertebral space, comprising:  
20 spacer engaging means for engaging the spacer; and occlusion means separate from said spacer engaging means for blocking an opening defined in the spacer.

55. The tool of claim 54 wherein said occlusion means includes a plate, said plate having a curved superior surface which approximates the outer surface of the spacer  
25 when said spacer engaging means is engaged to the spacer and said occlusion means is blocking the opening of the spacer.



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56. The tool of claim 54 wherein said spacer engaging means includes a post for engaging a hole in the spacer.

57. The tool of claim 56 wherein said post is threaded for mating engagement with a threaded hole in a spacer.

5 58. The tool of claim 56 wherein said post is a hex for mating engagement with an internal hex in a spacer.

59. The tool of claim 74 wherein said spacer engaging means is a pair of prongs having opposite, facing spacer engaging members for grasping an outer surface of the spacer.

10 60. A driving tool for implanting an interbody spacer in a space between adjacent vertebrae, the spacer including a body defining a chamber and an opening in communication with the chamber, the body having a pair of arms facing one another and forming a mouth to the chamber, and an anterior  
15 surface defining a tool engaging hole, the tool comprising:  
spacer engaging means for engaging the tool engaging hole; and  
occlusion means for blocking said mouth.

20 61. The tool of claim 60 further comprising a housing and wherein said occlusion means is extendable from said housing.

62. The tool of claim 60 wherein said spacer engaging means is a threaded post for threading engagement with the tool engaging hole.

25 63. A method for fusing two adjacent vertebrae, comprising the steps of:  
providing a spacer, the spacer including a body having a

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wall, said wall having an outer surface and defining a chamber and an opening in communication with said chamber, and a channel defined in said wall in communication with said chamber and said outer surface;

5       preparing the vertebrae and the intervertebral space between the vertebrae to receive the spacer;

      placing the spacer into the intervertebral space after the preparing step so that the opening is in communication with at least one of the vertebrae; and

10       packing osteogenic material into the channel after the placing step.

64. A method for fusing two adjacent vertebrae, comprising the steps of:

15       providing a spacer, the spacer including a body having a wall, said wall having an outer surface and defining a chamber and an opening in communication with said chamber, and a channel defined in said wall in communication with said chamber and said outer surface;

20       preparing the vertebrae and the intervertebral space between the vertebrae to receive the spacer;

      packing osteogenic material into the chamber;

      blocking the channel; and

25       placing the spacer into the intervertebral space after the blocking step so that the opening is in communication with at least one of the vertebrae.

65. The method of claim 64 further comprising:

30       implanting a second spacer into the intervertebral space after the placing step, the second spacer having a body having a wall, said wall having an outer surface and defining a chamber and an opening in communication with said chamber, and a channel defined in said wall in communication with said chamber and said outer surface; and

      orienting the first spacer and the second spacer so that

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the channels of the first and second spacers face one another.

66. The method of claim 65 further comprising packing an osteogenic material into the channels of the first and second spacers.

67. The method of claim 64, further comprising providing a tool of claim 27; engaging the spacer engager of the tool to the spacer; and wherein the blocking step includes extending the occlusion member to block the channel.

68. The spacer of claim 1 wherein said body is composed of a metal, a ceramic, a polymer or a composite or alloy thereof.

69. The spacer of claim 13 wherein said body is composed of a metal, a ceramic, a polymer or a composite or alloy thereof.

70. The spacer of claim 1 wherein said outer surface includes a curved portion and a flattened portion.

71. The spacer of claim 13 wherein said body further comprises an outer surface that defines a curved portion and a flattened portion.

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/11159

### A. CLASSIFICATION OF SUBJECT MATTER

IPC 6	A61F2/44	A61F2/46	A61B17/86	A61B17/16	A61B17/32
	A61L27/00	B23G5/00			

According to International Patent Classification (IPC) or to both national classification and IPC

#### B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

### C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	US 4 950 296 A (MCINTYRE) 21 August 1990	1,5-7, 11,12, 23,25, 27,68,70
A	see column 2, line 22 - column 3, line 4	10,13, 18-20, 22,26, 28,37-40
Y	WO 96 28118 A (KUSLICH) 19 September 1996	1,5-7, 11,12, 23,25, 27,68,70
A	see page 8, line 30 - page 9, line 7; figures 10-13	13,17,20

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

<sup>o</sup> Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

15 September 1998

Date of mailing of the international search report

02.10.98

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# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/11159

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 877 020 A (VICH) 31 October 1989  see the whole document ---	2,4,14, 16,21, 24,30, 32,34, 42,46, 48,54,60
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A	GB 2 207 607 A (A W SHOWELL (SURGICRAFT)) 8 February 1989 see the whole document ---	5,17,25, 27
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A	EP 0 734 703 A (DANEK MEDICAL) 2 October 1996 cited in the application ---	
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## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 98/11159

### Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 63-67  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

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